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EXAMINER

BENNETT, RACHEL M

| ART UNIT | PAPER NUMBER |
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1615

DATE MAILED: 05/20/2003

28

Please find below and/or attached an Office communication concerning this application or proceeding.

**Notice of Allowability**

Application No.

09/685,850

Examiner

Lakshmi S Channavajjala

Applicant(s)

PEFFLY ET AL.

Art Unit

1615

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 6-22-04.
2. ☒ The allowed claim(s) is/are 1-13, 15-33, 35-46 and 53-69.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

### **INTRODUCTION**

The claims are directed to a composition, an applicator and composition combination, and methods of treating the scalp or animal skin. Because, for each ground of rejection, the claims stand or fall together,<sup>1</sup> (Brief, p. 2) we select one claim to represent the issues on appeal for each rejection. 37 CFR § 1.192(c)(7)(2001). We select claims 1, 14, 19, and 41 and those claims are reproduced below:

1. A scalp cosmetic composition comprising:

- a) from about 40% to about 99% by weight of a volatile liquid having a vapor pressure greater than 23.7mmHg as measured at 25°C, and
  - b) from about 0.005% to about 20% by weight of a skin active agent,
  - c) from about 0.1% to about 20% by weight of a liquid humectant,
- wherein the composition is a leave-on composition that is substantially free of cleansing surfactants and is applied directly to the scalp.

14. The composition of Claim 1 wherein the composition is contained within an applicator having a plurality of openings through which the composition is applied directly to the scalp.

19. The composition of Claim 1 wherein the skin active agent comprises allantoin.

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<sup>1</sup>We take Appellants' statement in the Brief that the claims stand or fall together to mean that, *for each ground of rejection*, the claims stand or fall together because Appellants have included a separate section of argument for each ground of rejection in the argument section of the Brief and the selection of one claim for each separately rejected group of claims is in accordance with 37 CFR § 1.192(c)(7).

41. A method of treating animal skin, said method comprising:

a) applying directly to the skin a cosmetic composition that is substantially free of cleansing surfactants and which contains

i) from about 40% to about 99% by weight of a volatile liquid having a vapor pressure greater than 23.7mmHg as measured at 25°C,

ii) from about 0.005% to about 20% by weight of a skin active agent, and

iii) from about 0.1% to about 20% by weight of a liquid humectant, and

b) allowing the applied composition to remain on the scalp for at least about 30 minutes after application.

The claims are rejected under 35 U.S.C. § 103(a). As evidence of unpatentability, the

Examiner relies upon the following prior art references:

|                                |           |               |
|--------------------------------|-----------|---------------|
| Yoshihara et al. (Yoshihara)   | 4,940,578 | July 10, 1990 |
| Kellett et al. (Kellett)       | 5,002,075 | Mar. 26, 1991 |
| McKay                          | 5,325,878 | July 5, 1994  |
| Kashibuchi et al. (Kashibuchi) | 5,565,207 | Oct. 15, 1996 |

The specific rejections are as follows:

1. Claims 1-12, 15-18, 21-32, 35-38, and 53-69 rejected under 35 U.S.C. § 103(a) as being unpatentable over Yoshihara (Answer, pp. 3-4);
2. Claims 13, 19, 20, 33, 39, and 40 rejected under 35 U.S.C. § 103(a) as being unpatentable over Kashibuchi (Answer, p. 6);
3. Claims 14 and 34 rejected under 35 U.S.C. § 103(a) as being unpatentable over Yoshihara in view of McKay (Answer, pp. 7-8); and

4. Claims 41-46 rejected under 35 U.S.C. § 103(a) as being unpatentable over Yoshihara in view of McKay and further in view of Kellett (Answer, p. 10).

We affirm with respect to the rejections numbered 1, 2, and 4, but reverse with respect to rejection number 3. Our reasons follow.

### ***OPINION***

#### ***Rejection 1: The Rejection of Claims 1-12, 15-18, 21-32, 35-38 and 53-69 over Yoshihara***

The Examiner rejects claims 1-12, 15-18, 21-32, 35-38, and 53-69 as unpatentable over Yoshihara. We select claim 1 to represent the issues on appeal for this rejection. Claim 1 is directed to a composition. The composition contains a volatile liquid, a skin active ingredient, and a humectant. The composition is substantially free of cleansing surfactants. The claim specifies particular ranges of concentration for the ingredients.

The Examiner makes findings of fact supporting the conclusion of *prima facie* obviousness (Answer, pp. 3-4). Appellants do not dispute that there is a case of *prima facie* obviousness but, instead, argue that such is overcome by their showing of unexpected results (Brief, p. 3). Specifically, Appellants rely upon a comparison between Example A and Example F presented in the Peffly Declaration (Table I). According to Appellants the comparison "shows the surprising benefit that a humectant (glycerine, in this case) can have on skin hydration." (Brief, p. 3).

There is no dispute here that Yoshihara suggests the combination of a volatile liquid (ethanol), a skin active ingredient (anti-dandruff agent), and a humectant (glycerin or dipropylene glycol). The difference between the claimed invention and the prior art involves the concentration ranges for the components of the composition. In such a situation, the applicant must show that the claimed range is *critical*, generally by showing that the claimed range achieves unexpected results relative what is taught in the prior art. *In re Woodruff*, 919 F.2d 1575, 1578, 16 USPQ2d 1934, 1936-37 (Fed. Cir. 1990); *see also In re Boesch*, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980) ("It is well settled that a prima facie case of obviousness may be rebutted 'where the results of optimizing a variable, which was known to be result effective, [are] unexpectedly good.'" (quoting *In re Antonie*, 559 F.2d 618, 620, 195 USPQ 6, 8-9 (CCPA 1977))).

We cannot say that Appellants' showing provides the required evidence of criticality with respect to the humectant concentration range claimed. Appellants' claims encompass any humectant in the concentration range of about 0.1 to about 20 wt%. Appellants showing is limited to glycerin at a concentration of 5 wt%. This one data point is insufficient for showing criticality for the entire genus of humectants throughout the entire claimed range.

We agree with the Examiner that the showing is not commensurate in scope with the claims (Answer, pp. 4-5). *See In re Kulling*, 897 F.2d 1147 1149, 14 USPQ2d 1056, 1058 (Fed Cir. 1990). While Appellants are correct that, in some instances, the probative value of a narrow range of data can be reasonably extended to prove the unobviousness of a broader claimed range,

such as when one of ordinary skill in the art could ascertain a trend in the exemplified data, *see In re Kollman*, 595 F.2d 48, 56, 201 USPQ 193, 199 (CCPA 1979), one data point does not provide any evidence of a trend. There is no adequate basis for reasonably concluding that the great number and variety of compositions encompassed by the claims would behave in the same manner as the sole tested composition of the comparison.

In addition, Appellants have not provided adequate evidence that one of ordinary skill in the art would have found the result to be an "unexpected result." The Peffly Declaration states that Example A demonstrated moisturization values "significantly better than untreated" and Example F, the comparative example, showed moisture levels "below that of untreated skin," but there is no declaratory statement pointed to by Appellants indicating that such a result would have been unexpected. The difference between the two examples is the presence of 5 wt% glycerin in Example A. In light of the fact that glycerin was known in the art to increase moisture through hydration, we cannot say that Appellants have sufficiently proven that the result obtained in Example A would have been unexpected to one of ordinary skill in the art.

On balance, the totality of the evidence supports the Examiner's ultimate conclusion of obviousness as per the requirements of 35 U.S.C. § 103(a).

***Rejection 2: The Rejection of Claims 13, 19, 20, 33, 39, and 40 over Kashibuchi***

The Examiner rejected claims 13, 19, 20, 33, 39, and 40 as unpatentable over Kashibuchi. We select claim 19 to represent the issues on appeal with respect to this rejection. Claim 19 is

dependent on claim 1, but claim 19 further requires the skin active agent be comprised of allantoin.

The Examiner's conclusion of *prima facie* obviousness is supported by the findings of facts made by the Examiner as evidenced by Kashibuchi (Answer, pp. 6-7).

Appellants argue that no *prima facie* case is established because "Kashibuchi does not use a volatile liquid in combination with a humectant and a skin active agent, as claimed by Appellants." (Brief, p. 4). We are not persuaded because, as found by the Examiner, Kashibuchi suggests the addition of ingredients customarily used in scalp moisturizers and lists alcohols as among such customary ingredients (Kashibuchi, col. 6, ll. 10-16). That ethanol, an alcohol, which according to Appellants' specification, meets the volatility requirements of the claimed volatile liquid, is such a customary ingredient is further indicated by Example 7 of Kashibuchi which specifically includes ethanol (Kashibuchi, Table 8, col. 15, l. 57). We agree with the Examiner that Kashibuchi suggests to one of ordinary skill in the art the formulation of a scalp moisturizer containing customarily used alcohols, such as ethanol, along with cell activators, such as allantoin, and humectants as these ingredients are listed in the reference for use in the scalp moisturizer (Kashibuchi, col. 5, l. 61 to col. 6, l. 27). Using the suggested ingredients as



directed by Kashibuchi in such concentrations as one of ordinary skill in the art would determine through routine experimentation results in a composition meeting the requirements of claim 19.<sup>2</sup>

Appellants rely upon the evidence of unexpected results presented in the Peffly Declaration in their attempt to overcome the *prima facie* case of obviousness. Again, Appellants rely upon the comparison of Example A with Example F presented in the Declaration as showing a significant improvement in moisturization with the addition of 5 wt% glycerin as a humectant. But Kashibuchi seeks to formulate a scalp moisturizer and suggests the inclusion of a humectant. Kashibuchi also indicates that the moisturizing properties of humectants were known to those of ordinary skill in the art at the time of the invention (Kashibuchi, col. 1, ll. 56-59). Moreover, Kashibuchi exemplifies concentrations of humectant, 15 wt% glycerin, within the claimed concentration range (Examples 1-4, Table 1, col. 7, ll. 32). As discussed above, in this situation, Appellants must demonstrate the criticality of the claimed range and one data point at 5 wt% glycerin does not suffice. The data is not commensurate in scope with the claims. Moreover, the showing does not establish that the result would have been unexpected to one of ordinary skill in the art.

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<sup>2</sup>Appellants' argument is directed to the limitations of claim 1 (Brief, p. 4). While it would have been prudent for the Examiner to reject claim 1, the Examiner did not do so. Therefore, we have reviewed the argument as it applies to claim 19, one of the claims actually rejected by the Examiner.

On balance, the totality of the evidence supports the Examiner's ultimate conclusion that the subject matter of claim 19 and those claims that stand or fall therewith would have been obvious to one of ordinary skill in the art at the time of the invention.

***Rejection 3: The Rejection of Claims 14 and 34 over Yoshihara and McKay***

Claims 14 and 34 are rejected over the combination of Yoshihara and McKay. These claims both require that the composition be contained within an applicator "having a plurality of openings through which the composition is applied directly to the scalp." McKay, according to the rejection, teaches the required applicator (Answer, p. 8).

As we explained in our Decision in Appeal No. 2004-0308, McKay does not describe or suggest the applicator of the claims. The claims require a particular positioning of the openings in the applicator: A positioning such that the composition is "applied directly to the scalp." In the specification, Appellants have particularly defined the phrase "applied directly": This phrase means that "the composition is applied to *primarily* to the scalp rather than to the hair." (specification, p. 4, ll. 3-7, emphasis added; see also p. 12, l. 22 to p. 13, l. 22). Direct application in the context of the claims requires that one be able to position the openings adjacent the scalp such as could be done with a comb such as that described in U.S. Patent 2,624,348 issued to Matson which has openings at the bottom of the tines. The groove of the dispensing comb of McKay is high in the comb at the base of the teeth 16 and designed for applying fluid to the hair, not primarily the scalp. The opening of McKay does not allow for direct application of

the composition to the scalp, the composition only reaches the scalp indirectly by flowing from the hair to the scalp.

The prior art combination, as advanced by the Examiner, therefore, does not describe all the limitations of the claims. Nor has the Examiner explained how those combinations would have suggested a structure encompassed by the claims to one of ordinary skill in the art. We, therefore, conclude that the Examiner has failed to establish a *prima facie* case of obviousness with respect to the subject matter of claims 14 and 34.

***Rejection 4: The Rejection of Claims 41-46 over Yoshihara, McKay and Kellett***

The Examiner has rejected claims 41-46 as unpatentable over Yoshihara, McKay, and Kellett. We select claim 41 to represent the issues on appeal. Claim 41 is directed to a method of treating animal skin which essentially involves applying the composition of claim 1 onto the skin such that the composition remains on the scalp for at least 30 minutes after application. With regard to Rejection 1, Appellants did not dispute that the composition of claim 1 would have been obvious to one of ordinary skill in the art in view of Yoshihara. Further, as is clear from Yoshihara, the composition is used in products such as scalp lotions which are applied after shampooing (Example 1) and, thus not washed away but left on. Yoshihara would have suggested to one of ordinary skill in the art the use of the leave-on treatment of claim 41. Moreover, Appellants do not present any new arguments directed to limitations contained in claim 41 (Brief, p. 7).

Because claims 42-46 stand or fall together with claim 41 and McKay and Kellett were applied to meet the limitations of dependent claims, there is no need here to address McKay or Kellett. We conclude that the Examiner has established a *prima facie* case of obviousness over the combination of Yoshihara, McKay, and Kellett with regard to the subject matter of claim 41 and those claims that stand or fall therewith.

Appellants again rely upon a showing of unexpected results presented in the Peffly Declaration. For the reasons we advanced in reference to the rejection of claim 1 over Yoshihara, we conclude that the totality of the evidence weighs in favor of a legal conclusion of obviousness.

#### ***OTHER ISSUES***

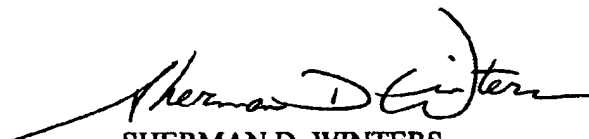
We have reversed the rejection of claims 14 and 34, but that does not necessarily mean those claims are allowable. *See In re Arkley*, 455 F.2d 586, 589, 172 USPQ 524, 527 (CCPA 1972). It may well be that there is a proper basis for rejecting the claims. We specifically call U.S. Patent 2,624,348 issued to Matson on January 6, 1953 to the Examiner's and Appellants' attention. Matson was submitted by Appellants in the Supplemental Information Disclosure Statement of November 22, 2002 (Paper No. 18). This reference seems to describe an applicator meeting the requirements of claims 14 and 34. The patentability of these claims in view of Matson in combination with prior art teaching or suggesting the composition of claim 1, from

which claim 14 depends, and the method limitations of claim 21, from which claim 34 depends, should be considered upon return of this application to the jurisdiction of the Examiner.

**CONCLUSION**

To summarize, the decision of the Examiner to reject claims 1-13, 15-33, 35-46 and 53-69 under 35 U.S.C. § 103(a) is affirmed, but the decision of the Examiner to reject claims 14 and 34 under 35 U.S.C. § 103(a) is reversed. Accordingly, we affirm-in-part.

**AFFIRMED-IN-PART**

  
SHERMAN D. WINTERS  
Administrative Patent Judge

  
WILLIAM F. SMITH  
Administrative Patent Judge

  
CATHERINE TIMM  
Administrative Patent Judge

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